PATENT
Customer No. 22,852
Attorney Docket No. 008358.0005-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Steffen Goletz, et al.	)	Group Art Unit: 1643
	)	
Serial No.: 10/522,087	)	Examiner: Hong Sang
	)	
Filed: July 26, 2005	)	
	)	Confirmation No.: 7596
For: METHOD FOR THE PRODUCTION OF AN IMMUNOSTIMULATING MUCIN (MUC1)	)	

VIA ELECTRONIC FILING
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In response to the office action dated June 1, 2007, enclosed is a petition for a five month extension of time and fee payment. The Examiner has required restriction under 35 U.S.C. § 121 between the following groups of claims:

Group 1 - Claim(s) 1-3, 7 and 9-11, drawn to a method for the production of a MUC1 molecule which is able to generate an immune response in humans, and a method for identification of a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 molecule, wherein the antibody is A76-A/C7.

Group 2 - Claim(s) 1-3, 7 and 9-11, drawn to a method for the production of a MUC1 molecule which is able to generate an immune response in humans, and a method for identification of a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 molecule wherein the antibody is VU-11E2.

Group 3 - Claim(s) 1-3, 7 and 9-11, drawn to a method for the production of a MUC1 molecule which is able to generate an immune response in humans, and a method for identification of a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 molecule, wherein the antibody is VU-11D1.

Group 4 - Claim(s) 1-3, 7 and 9-11, drawn to a method for the production of a MUC1 molecule which is able to generate an immune response in humans, and a method for identification of a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 molecule, wherein the antibody is BC4E549.

Group 5 - Claim(s) 1-3, 7 and 9-11, drawn to a method for the production of a MUC1 molecule which is able to generate an immune response in humans, and a method for identification of a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 molecule, wherein the antibody is VU-12E1.

Group 6 - Claim(s) 1-3, 7 and 9-11, drawn to a method for the production of a MUC1 molecule which is able to generate an immune response in humans, and a method for identification of a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 molecule, wherein the antibody is VU-3D1.

Group 7 - Claim(s) 1-3, 7 and 9-11, drawn to a method for the production of a MUC1 molecule which is able to generate an immune response in humans, and a method for identification of a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 molecule, wherein the antibody is b-12.

Group 8 - Claim(s) 4-6, 7 and 9-11, drawn to a method for producing cells comprising a MUC1 molecule which is able to generate an immune response in humans, and a method of identifying cells comprising a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 cells, wherein the antibody is A76-A/C7.

Group 9 - Claim(s) 4-6, 7 and 9-11, drawn to a method for producing cells comprising a MUC1 molecule which is able to generate an immune response in humans, and a method of identifying cells comprising a

MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 cells, wherein the anti body is VU-11E2.

Group 10 - Claim(s) 4-6, 7 and 9-11, drawn to a method for producing cells comprising a MUC1 molecule which is able to generate an immune response in humans, and a method of identifying cells comprising a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 cells, wherein the antibody is VU-11D1.

Group 11 - Claim(s) 4-6, 7 and 9-11, drawn to a method for producing cells comprising a MUC1 molecule which is able to generate an immune response in humans, and a method of identifying cells comprising a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 cells, wherein the antibody is BC4E549.

Group 12 - Claim(s) 4-6, 7 and 9-11, drawn to a method for producing cells comprising a MUC1 molecule which is able to generate an immune response in humans, and a method of identifying cells comprising a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 cells, wherein the antibody is VU-12E1 .

Group 13 - Claim(s) 4-6, 7 and 9-11, drawn to a method for producing cells comprising a MUC1 molecule which is able to generate an immune response in humans, and a method of identifying cells comprising a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 cells, wherein the antibody is VU-3D1.

Group 14 - Claim(s) 4-6, 7 and 9-11, drawn to a method for producing cells comprising a MUC1 molecule which is able to generate an immune response in humans, and a method of identifying cells comprising a MUC1 molecule which is able to generate an immune response in humans, a method for producing a pharmaceutical composition comprising said MUC1 cells, wherein the antibody is b-12.

Groups 15-28

Claim(s) 8-12, drawn to a method for producing an antibody, a method for producing a pharmaceutical composition comprising the antibody, the method comprises carrying out the steps of the method according to groups 1-14.

i .e.

Group 15 comprising carrying out the steps of group 1
Group 16 comprising carrying out the steps of group 2
Group 17 comprising carrying out the steps of group 3
. . .
Group 28 comprising carrying out the steps of group 14

Group 29 - Claim(s) 13, drawn to purified MUC1 molecule which has an immunostimulating effect in humans.

Applicants provisionally elect, with traverse, to prosecute Group I (claims 1-3, 7 and 9-11). These claims are drawn to a method for the production of a MUC1 molecule which is able to generate an immune response in humans, a method for identification of a MUC1 molecule which is able to generate an immune response in humans, and a method for producing a pharmaceutical composition comprising said MUC1 molecule wherein the antibody is A76-A/C7.

Applicants traverse the restriction of claims 1-13 into 29 separate groups on the ground that it is improper for the Examiner to refuse to examine Applicants' generic invention. If the Examiner considers the genus too broad to search, he can require a species election. If the Examiner considers the genus too broad to be supported by the specification, he can issue an enablement rejection. Restricting the claims so that each group contains only a single species destroys the genus and deprives Applicants of the opportunity to have the full scope of their invention examined.

The restricted claims are drawn to methods for the production or identification of a MUC1 molecule, MUC1 molecules purified using this method, and use of these MUC1 molecules (claims 1-3, 7, 11, and 13); methods for producing or identifying cells comprising a MUC1 molecule (claims 4-7); methods for producing an antibody, and use of the antibody (claims 8, 12); and methods for producing a pharmaceutical composition

comprising MUC1 molecules (claims 9-11). Each of the methods recited in the claims relies on generic antibodies having specifically defined characteristics.

Nowhere in the restriction requirement does the Examiner indicate that he will ever consider any one of the claimed generic methods, which can be practiced using any antibody having the specific properties recited in the claims, and exemplified by the specific antibodies recited in claim 7. This is an improper use of restriction practice.

The Examiner has argued that the inventions of Groups 1-29 do not relate to a single general inventive concept under PCT Rule 13.1. The Examiner first alleges that the "special technical feature linking the Groups 1-29 appears to be the purified MUC1 molecule." Office Action at 5. The Examiner then alleges that the purified molecule is allegedly shown in the prior art. *Id.* Based on these allegations, the Examiner concludes that the purified MUC1 molecule cannot be a special technical feature under PCT Rule 13.2 because it is shown in the prior art. *Id.*

However, contrary to the Examiner's assertion, the technical feature that unifies all of the claimed methods is the use of antibodies defined by specific properties, not purified MUC1 molecules. In fact, the Examiner's assertion is illogical in view of the actual restriction, which is based on the specific antibodies recited in claim 7. The Examiner's reliance on Ryuko et al., *Tumor Biology* 21:197-210 (2000) to suggest that the technical feature linking the claims is not novel is equally unparseable. Ryuko refers to *the generation and characterization of a new MUC1 monoclonal antibody* and not the production of purified MUC1 molecules. Moreover, because Ryuko does not teach or suggest use of antibodies having the specific properties recited in the claims to identify and isolate a MUC1 molecule (or to produce cells containing a MUC1 molecule) that is

able to generate an immune response, it is irrelevant to the contribution made by the inventor over the prior art. Consequently, Ryuko has no bearing on whether the common technical feature of the claims provides a contribution over the art.

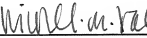
For these reasons, Applicants respectfully request the requirement be withdrawn and that Groups 1-29 be examined together on their merits in the application. Alternatively, Applicants request that the restriction between Groups 1-14 and 29 be withdrawn and that these groups be examined together because the claims share a special technical feature, specifically the use of antibodies having specific characteristics to identify and isolate a MUC1 molecule -- or to produce cells comprising a MUC1 molecule -- that is capable of generating an immune response.

Applicants believe that any extension of time required for entry of this response is accounted for in the accompanying petition for extension of time. However, in the event of an error, please grant any extensions of time required to enter the response and/or charge any additional required fees to deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: December 3, 2007

By: 
Nicole L. M. Valtz
Reg. No. 47,150